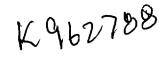


GAYMAR INDUSTRIES, INC.



APR 30 1997

## Premarket Notification [510(K)] Summary

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**Date Summary** 

Prepared:

**January 30, 1997** 

**Device Name:** 

**CLINI-DYNE Rotational Therapy System** 

Common Name:

Rotation/Low Air Loss System

Classification Name:

Alternating Pressure Air Flotation Mattress per

21 CFR, Section 880.5550

**Predicate Device:** 

CLA 1400 System

#### **Intended use of Device:**

The CLINI-DYNE rotational/low air loss system is a patient rotation, pressure relieving support system used for the treatment and prevention of decubitus ulcers, urinary tract blockage, to aid circulation and for complications associated with immobility.

**Description:** 

The CLINI-DYNE Rotational Therapy System consists of an electromechanical inflation pump control unit which is connected to a mattress with cells (air filled bladders) through hose assemblies connected to the inflation pump. The system affords programmed patient position changes by gently turning the patient from supine to left side or right side and back to supine position when staff is unable to do so or needs assistance.

## Substantial Equivalence:

The following tables, CLINI-DYNE substantial equivalence matrix and the safety testing comparison table, summarize the technological characteristics and the nonclinical performance data upon which the substantial equivalence submission was made to the Food and Drug Administration.

### CLINI-DYNE SUBSTANTIAL EQUIVALENCE MATRIX

7/11/96

CLA-1400 (Predicate) CLD-1000

PERFORMANCE			
Patient Support Surface	Overlay	Mattress	
	Blower	Electro-mechanical reciprocating	
Air Source		pump	
Pressure control	Microprocessor controlled	Microprocessor controlled	
mechanism	pressure relief valve	pressure relief valve	
Voltage	120v 60Hz Nominal	120v 60Hz Nominal	
Ambient	60-90°F	60-90°F	
Tissue interface pressure	Pressure relief	Pressure relief	
measurements			
Rotation angle	0-45°	0-40° **	
Safety			
Maximum allowable	Mechanical relief valve (55-60	Mechanical relief valve (56 mmHg)	
pressure controlled by	mmHg)		
CPR Deflate mechanism	Quick-disconnect feature of hose	Remove panel at mattress	
	from pump		
Physical			
<u>char</u> acteristics			
Construction (Patient	Air filled cells used as an overlay	Air filled cells contained in a foam	
support surface)	·	crib used as a mattress	
Function &			
Intended uses			
Type of therapy provided	Treatment of the diseases of	Treatment of the diseases of	
	immobility and treatment of	immobility and treatment of	
ł	pressure ulcers	pressure ulcers	
(Primary) Target	Acute care and alternate care	Acute care and alternate care	
population	settings	settings	
Life Expectancy (pump)	Reusable*	Reusable*	
Life Expectancy (cell)	Resusable*	Reusable*	
Product Labeling	Refer to TAB C - LABELING	Refer to TAB B - LABELING	
Approvals	UL 544	UL 2601-1 (submitted)	

<sup>\*</sup> Cleanable using suggested disinfectants and cleaning agents.

<sup>\*\*</sup> Dependent on physical characteristics of the patient. (40° minimum when set at maximum angle setting for each patient.)

# **COMPARISON OF MAJOR CHARACTERISTICS**

<u>Characteristic</u>	CLA-1400 (PREDICATE)	CLD-1000	
Alerts Audible Alerts	yes	yes	
Alert Silence (minutes)	30	no	
Head of Bed Elevation Alert	yes		
Out of Rotation Alert	yes	no*	
Siderail UP/Down Alert	yes	no*	
Visual Alerts	yes	yes	
Rotation			
Automatic Left Only	yes	yes	
Automatic Left to Right	yes	yes	
Automatic Right Only	yes	yes	
Center Only (no rotation)	yes	yes	
Manual Left Only	yes	yes	
Manual Right Only	yes	yes	
Var.Angle, Min.range (degrees)	0-45	0-45	
Variable Rate	yes	yes	
Rotation Cycle Times (minutes)	90, 30, 10, 2	60, 45, 30, 15	
Cushion			
Placed onto Hospital Bed	yes	no (mattress replacement)	
CPR Deflate	yes	yes	
Low Air Loss	yes	yes	
Pressure Relieving	yes	yes	
Support Surface Inflation Control	yes	yes	
Disposable Covers	yes	no**	
Disposable Support Surface	yes	no**	
Footboard/Foot Support Cushion	yes	yes	
Air Control Pump			
120 Volt AC	yes	yes	
60 Hz	yes	yes	
Amperage	1-5	1	
Control Panel Lock-out	yes	yes	
Microprocessor Control	yes	yes	
U.L. Listed	yes	yes	
Weight (lbs.)	25	19	

<sup>\*</sup> See Substantial Equivalence

<sup>\*\*</sup>Reusable mattress

#### VI. SAFETY SUMMARY

# **Safety Testing Comparison Table**

		CLA 1400	CLD 1000
Biocompa	tibility		
a)	primary skin irritation	pass	pass
<b>b</b> )	delayed contact sensitization	pass	pass
<b>c</b> )	cytotoxicity	pass	pass
Tissue Inte	erface Testing	pass	pass
Flammabil	ity	pass	pass
UL Approvals		UL 544	UL 2601-1 (pending)
Alerts			
a)	hi/low pressure	yes	yes
<b>b</b> )	out of range	yes	yes